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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,569	02/13/2004	Alan G. Maloney	29954-701.201	8257

21971 7590 04/09/2009
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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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04/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/779,569	Applicant(s) MALONEY ET AL.	
	Examiner RUSSELL S. NEGIN	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-130, 132-139 and 141-145 is/are pending in the application.
- 4a) Of the above claim(s) 134-136 and 143-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128-130, 132, 133, 137-139, 141 and 142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Comments

Applicants' amendments and request for reconsideration in the communication filed on 16 January 2009 are acknowledged and the amendments are entered.

Claims 134-136 and 143-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 September 2006.

Claims 128-130, 132-139, and 141-145 are pending, and claims 128-130, 132-133, 137-139, and 141-142 are examined in the instant Office action.

Withdrawn Rejections

The rejections of claims 128-130 and 132-133 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter are withdrawn in view of amendments filed to the instant set of claims on 16 January 2009.

Claim Rejections - 35 USC § 112

The following rejections are NEWLY APPLIED and necessitated by applicant's amendments:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

WRITTEN DESCRIPTION

Claims 128-130 and 132-133 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended step c of claim 128 recites:

...searching the medical literature database for medical literature articles relating to one or more identifiers **using computer code that executes** an evidence based medicine filter...

While the instant specification discloses using computer code to search the medical literature database for medical literature articles relating to the one or more identifiers using an evidence based medicine filter (see Figures 1 and 3 and paragraphs 22 and 25), the instant specification does not disclose the actual execution of an evidence based filter using computer program code. In other words, the specification shows how to use computer code to search a medical literature database for articles with identifiers, wherein the method or system employs (or uses) an evidence based medicine filter; the specification does NOT demonstrate how to execute the evidence based filter itself using a computer program code (as recited in the amended claim). Consequently the amendment to step c of instant claim 128 constitutes NEW MATTER.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is reiterated:

35 U.S.C. 103 Rejection #1:

Claims 128-130, 132-133, 137-139 and 141-142 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiGregorio et al. [Obesity Surgery, volume 11, 2001, pages 318-326] in view of Siffert et al. [Journal of the American Society of Nephrology, volume 10, 1999, pages 1921-1930] in view of Rappaport [US PG PUB 2002/07285 A1, published 17 January 2002; filed 3 January 2001].

Independent claim 137 is drawn to a computer readable medium comprising:

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- a) computer code that receives a genetic profile of a patient;
- b) computer code that translates the genetic profile into one or more identifiers of a medical classification system for a medical literature database;
- c) computer code that searches the medical literature database for medical literature articles relating to the one or more identifiers using an evidence based medicine filter;
- and d) computer code that identifies the articles on a user interface;

wherein the computer readable medium is not a carrier wave.

Claims 138-139 are further limiting wherein the genetic profiles include a nucleic acid sequence and an SNP.

Claims 141-142 are further limiting wherein the medical literature articles are clinical articles or validated treatments.

Claims 128-130 and 132-133 are drawn to similar subject matter as claims 137-139 and 141-142, except as a METHOD of identifying medical literature performed by a computer system.

The article of DiGregorio et al. studies how to improve systematic searches for enhanced decision-making and clinical outcomes; specifically, DiGregorio et al. studies quality of life after obesity surgery using an evidence based medicine literature review.

DiGregorio et al. translates the result of a patient positive for obesity into one or more identifiers for a medical literature database. Specifically, the Cochrane library and the respective identifiers translated from an "obesity positive" population (i.e. obesity keywords) are listed in Table 2 on page 323 of DiGregorio et al. The results of

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searching the Cochrane Library (i.e. a specific evidence based database on medicine) are displayed as number of "hits" in the right column of Table 2 of DiGregorio et al.

The Cochrane library is an evidence based literature database. As discussed in the final full paragraph of the second column of page 323 of DiGregorio et al., the only literature in the Cochrane database are evidence based. Consequently, when compared with a more generic database (i.e. MEDLINE), the Cochrane Library results in a reduced, but more focused (i.e. filtered) number of hits. The articles are identified on a user interface such as the table depicted in page 323 of DiGregorio et al. Consequently, as the medical literature of the Cochrane library is searchable and classified (i.e. in Table 2) in response to the number of hits obtained, the Cochrane library is interpreted to be a medical literature classification database.

While DiGregorio et al. depicts searches related to clinical and multiple possible validated surgical treatment techniques; i.e. searches performed using evidence (data) based medical filters (see Table 2 of Gregorio et al.) for patients who exhibit the symptomatic traits of obesity, DiGregorio et al. does not obtain actual genetic profiles from such patients.

The article of Siffert et al. teaches worldwide ethnic distribution of the G protein beta-3 subunit 825T allele and its association with obesity in Caucasian, Chinese, and Black African individuals.

Specifically, Table 1 on page 1923 of Siffert et al. correlates genotypes as a result of the C825T SNP (i.e. genetic profiles) to categories of body weight (i.e. underweight, normal weight, overweight, and obese). These categories or

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characteristics act as translations of genotypes of individuals into keywords, such as "obese" which are utilized in the study of DiGregorio et al. to search the Cochrane literature database.

The prior art of DiGregorio et al. and Johnson do not teach the computerized limitations of the instant claims (i.e. computer system, computer readable media, computer code).

The publication of Rappaport teaches a method, apparatus, and system for providing targeted information in relation to laboratory and other medical services.

Specifically Figure 2 of Rappaport illustrates the automated (i.e. computerized) aspects of method, apparatus, and system for providing targeted information.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the evidence based obesity data search of DiGregorio et al. by use of the genetic profiles classification system of Siffert et al. wherein the motivation would have been that while DiGregorio et al. has the advantage of proposing treatments that would most probably result in the best quality of life after the treatment [see title and abstract of DiGregorio], the genetic profiles of Siffert et al. give a more quantitative extent of the genetic component to the observed obesity [see, for example Table 1 of Siffert et al.] in order to better relate correlations of genotype frequencies in specific races of the population with obesity indicators or searchable keywords. It would have been further obvious to someone of ordinary skill in the art at the time of the instant invention to modify the obesity data search of DiGregorio et al. and the genetic profiles of Johnson by use of the automated database system of Rappaport wherein the

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motivation would have been that it would have been obvious to automate the database searching algorithm of DiGregorio et al. based on the obesity profiles measured in Johnson to result in a more expedient and accurate process or product (see, for example, Figure 2 of Rappaport).

Response to Arguments:

Applicant's arguments filed 9 January 2009 have been fully considered but they are not persuasive.

Applicant argues on page 7 of the Remarks that the article of Siffert et al. only suggests that the genetic profiles "MAY contribute to obesity" without a direct teaching of a genetic profile that does contribute to obesity. This argument is not persuasive because the teaching of Siffert et al. is relied upon for teaching genetic profiling; the phrase pointed to by applicant at least suggests that his profiling may be combined with a study of obesity such as that taught by DiGregorio et al., therefore the examiner maintains that the claims are made obvious by the combination of references for the reasons set forth above. One of skill in the art would reasonably have anticipated success in combining the teachings of DiGregorio et al. and Siffert et al. because the in silico Boolean searches for obesity of DiGregorio et al. are generally applicable to the results of the generic profiles and expressions related to obesity of Siffert et al.

Applicant additionally argues on page 7 of the Remarks that DiGregorio et al. does not show searching the medical literature database for medical literature articles relating to the one or more identifiers using computer code that executes a medicine

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based filter. This is not persuasive because (as explained above) DiGregorio et al. depicts searches related to clinical and multiple possible validated surgical treatment techniques; i.e. searches performed using evidence (data) based medical filters (see Table 2 of Gregorio et al.) for patients who exhibit the symptomatic traits of obesity.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices

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published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).

The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/
Russell S. Negin
5 April 2009

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631